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10/584,819	06/14/2007	Samuel K. Sia	H0498.70211US02	5917
23628	7590	02/03/2009	EXAMINER	
WOLF GREENFIELD & SACKS, P.C.			YU, MELANIE J	
600 ATLANTIC AVENUE			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,819	Applicant(s) SIA ET AL.	
	Examiner MELANIE YU	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46, 48, 51-53 and 56-85 is/are pending in the application.
- 4a) Of the above claim(s) 1-44 and 56-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45, 46, 48, 51-53 and 72-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/27 and 12/29</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group IV, claims 45-55, in the reply filed on 14 November 2008 is acknowledged. The traversal is on the ground(s) that applicant's believe that a single search and examination would not place undue burden on the examiner. This is not found persuasive because as described in the requirement for restriction mailed on 14 October 2008, there is no common special technical feature that links the groups.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-44 and 56-71 have been withdrawn as being drawn to a non-elected invention.

Claims 45, 46, 48, 51-53 and 72-85 read on the elected invention and are examined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 45 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Vo-Dinh (US 7,267,948).

Vo-Dinh teaches a method comprising: flowing a fluid sample over a surface of a microfluidic channel (microchannels feed into a microchamber that has an inlet and outlet, and is therefore also considered a microchannel, col. 23, lines 36-52); allowing a sample component to bind with a binding partner (col. 13, lines 15-22) disposed on the surface of the microfluidic channel (col. 4, lines 12-13); and accumulating an opaque material on a portion of the surface of the microfluidic channel (platform is covered with silver colloids, col. 18, line 63-col. 19, line 7).

With respect to claim 51, Vo-Dinh teaches the binding partner being an antibody (col. 4, lines 3-9) and the sample component being an antigen (col. 13, lines 15-17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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3. Claims 45, 52, 53, 72-79 and 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gallagher et al. (US 2003/0064507) in view of Mayer et al. (US 2003/0215865).

Gallagher et al. teach a method comprising: flowing a fluid sample over a surface of a microfluidic channel (introduction of sample, par. 91); allowing a sample component to bind with a binding partner (par. 75) disposed on the surface of the microfluidic channel (microfluidic chamber has inlet and outlet and is therefore considered a channel, par. 104; chamber has array of binding molecules, par. 47; binding molecules attached to substrate, par. 20); and labeling the sample component with colloidal gold labels (par. 217), but fail to teach accumulating an opaque material on a portion of the surface of the microfluidic channel.

Mayer et al. teach flowing a fluid sample over a surface and allowing a sample component to bind with a binding partner disposed on the surface (sandwich assay, targets bind with receptors, par. 10); attaching a metal colloidal label to the sample component (target labeled with metal nanoparticle, par. 10); and accumulating a silver opaque material on a metal colloid on a portion of the surface by electroless deposition (size of particle is increased through Ag electroless plating, therefore opaque silver is accumulated, par. 10), in order to provide an optical contrast for detection.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Gallagher et al., accumulating an opaque material on a portion of the surface as taught by Mayer et al., in order to enhance the sensitivity of detection of the label.

With respect to claims 52 and 53, Gallagher et al. teach the fluid passed over a plurality of surfaces wherein each of the surfaces is associated with a different binding partner (array wherein each array element is a different surface and a different binding partner is immobilized on each surface element, par. 74).

Regarding claims 76 and 77, Gallagher et al. teach the metal colloid comprising a gold conjugated antibody (par. 217).

With respect to claim 78, Gallagher et al. in view of Mayer et al. teach the opaque material deposited over a the metal colloids which are immobilized in each of the array regions of Gallagher et al. (channel of Gallagher et al. has a width between 2 and 500 microns, therefore the array, which fills the width of the channel would have a dimension of at least 10 microns and the opaque material is deposited over a region having a dimension of at least 10 microns, par. 91).

Regarding claim 79, Gallagher et al. teach that the materials contacted with the array are flowed over the array (par. 89), therefore the opaque material taught by Mayer et al. would also be flowed over the array.

With respect to claims 83 and 85, Gallagher et al. teach the sample being whole blood or urine (par. 131).

Regarding claim 84, Gallagher et al. teach at least one cross-sectional dimension being 2-50 microns, which is encompassed by the recited range of less than 100 microns (par. 91).

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4. Claims 46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gallagher et al. (US 2003/0064507) in view of Mayer et al. (US 2003/0215865), as applied to claim 45, further in view of Remacle et al. (US 2002/0177144).

Gallagher et al. in view of Mayer et al. teach detecting fluorescence of colloidal gold labels, but fail to teach determining the opacity of the opaque material by measuring light transmittance or light reflectance.

Remacle et al. teach detection of colloidal gold labels by irradiating with light (light beam, par. 108) and measuring light transmission (par. 108), in order to provide a detectable change that indicates binding.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Gallagher et al. in view of Mayer et al., irradiating labels with light and detection using light transmittance as taught by Remacle et al., in order to provide detection with less false positives and negatives.

5. Claims 46 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gallagher et al. (US 2003/0064507) in view of Mayer et al. (US 2003/0215865), as applied to claim 45, further in view of Haugland et al. (US 6,967,251).

Gallagher et al. in view of Mayer et al. teach detecting fluorescence of colloidal gold labels, but fail to teach determining the opacity of the opaque material by measuring light transmittance or light reflectance.

Haugland et al. teach detection of colloidal gold labels with by irradiating with light (col. 16, lines 15-24) and measuring light reflectance or fluorescence (col. 14, line 50-col. 15, line 4), in order to provide a detectable change that indicates binding.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Gallagher et al. in view of Mayer et al., irradiating colloidal gold labels with light and detection using light reflectance as taught by Haugland et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent detection techniques and since the same expected detection would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of detectors.

6. Claim 80 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gallagher et al. (US 2003/0064507) in view of Mayer et al. (US 2003/0215865), as applied to claim 45, in light of Krulik et al. (US 5,318,621).

Gallagher et al. in view of Mayer et al. teach opaque material formed by flowing a metal solution and deposition by electroless deposition, but fail to specifically teach the solution comprising a silver salt. However, Krulik et al. teach that silver electroless plating solutions comprise silver nitrate (col. 1, line 2, line 6), which is a silver salt. Therefore the silver electroless plating solution of Mayer et al. would comprise silver nitrate.

7. Claim 81 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gallagher et al. (US 2003/0064507) in view of Mayer et al. (US 2003/0215865), as applied to claim 72, further in view of Kaler et al. (US 6,333,200).

Gallagher et al. in view of Mayer et al. teach measuring the fluorescence of the gold particles and accumulated metal to enhance detection, but fail to teach measuring the conductivity of the accumulated metal.

Kaler et al. teach a silver enhancement of gold nanoparticles (col. 2, lines 17-24) and measuring the conductivity of the accumulated metal (col. 2, lines 27-33), in order to provide direct electrical readout.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Gallagher et al. in view of Mayer et al., detection of the conductivity of the accumulated material as taught by Kaler et al., in order to provide results that are directly read by a computer and are accurate for very small samples.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Patent Examiner, Art Unit 1641